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(71) Applicant: EXOGEN, INC. [US/US]; 10 Constitution Avenue, P.O. Box 6860, Piscataway, NJ 08855 (US).

(72) Inventors: TALISH, Roger, J.; 5 Harman Court, Hillsborough, NJ 08876 (US). WINDER, Alan, A.; 56 Patrick Road, Westport, CT 06880 (US).

(74) Agents: CARTER, David, M. et al.; Dilworth & Barrese, LLP, 333 Earle Ovington Boulevard, Uniondale, NY 11553 (US).

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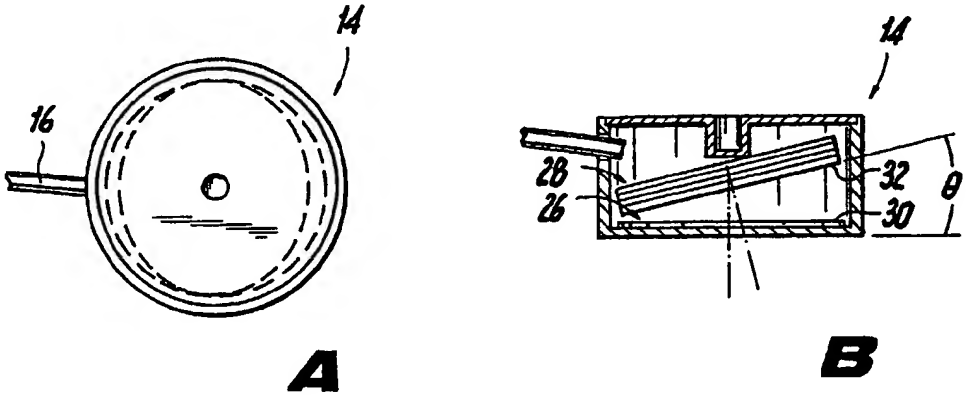

(57) Abstract: The invention relates to apparatus and method for ultrasonically and electromagnetically treating tissue to treat, for example, traumatized tissue or a bone injury. The apparatus includes at least one ultrasonic transducer assembly (26) and at least one electromagnetic coil assembly (28) configured to cooperate with a placement module for placement in proximity to the treatment area. The apparatus also utilizes a portable main operating unit constructed to fit within a pouch or carrying case worn by the patient. In operation, at least one ultrasonic transducer and at least one elecromagnetic coil are activated by transmitting control signals to the placement module from the main operating unit. The activation of the at least one ultrasonic transducer causes ultrasonic waves to be propagated toward the treatment area which are modulated by electrostatic and magnetic forces generated by the at least one electromagnetic coil. The activation of the at least one ultrasonic transducer and the at least one electromagnetic coil may be performed at the same time or at different times for varying periods.

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APPARATUS AND METHOD FOR ULTRASONICALLY AND ELECTROMAGNETICALLY TREATING TISSUE

PRIORITY

This application claims priority to a U.S. Provisional Application No. 60/135,224 filed on May 20, 1999 by Talish et al., the contents of which are incorporated herein by reference.

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to apparatus and method for ultrasonically and electromagnetically stimulating treating tissue, for example, traumatized tissue or a bone injury. More particularly, the present invention relates to apparatus and methods which utilize an ultrasonic transducer assembly in combination with an electromagnetic coil assembly to treat tissue.

2. Description of the Related Art

The use of ultrasound to therapeutically treat and evaluate tissue and bone injuries is known. Impinging ultrasonic pulses having appropriate parameters, e.g., frequency, pulse repetition, and amplitude, for suitable periods of time and at a proper external location adjacent to a tissue or bone injury has been determined to accelerate the natural healing of, for example, tissue tears, bone breaks and fractures.

U.S. Patent No. 4,530,360 to Duarte describes a basic non-invasive therapeutic technique and apparatus for applying ultrasonic pulses from an operative surface placed on the skin at a location adjacent a bone injury. To apply the ultrasound pulses during treatment an operator must manually hold the applicator in place until the treatment is complete.

The Duarte patent as well as U.S. Patent No. 5,520,612 to Winder et al. describe ranges of RF signal for creating the ultrasound, ultrasound power density levels, ranges of duration for each ultrasonic pulse, and ranges of ultrasonic pulse frequencies.

U.S. Patent No. 5,003,965 to Talish et al. relates to an ultrasonic body treatment system having a body-applicator unit connected to a remote control unit by sheathed fiber optic lines. The signal controlling the duration of ultrasonic pulses and the pulse repetition frequency are generated apart from the body-applicator unit. Talish et al. also describes a mounting fixture for attaching the body-applicator unit to a patient so that the operative surface is adjacent the skin location.

While the systems described in these patents relate to methods and apparatus for ultrasonic diagnosis and/or treatment of hard and soft tissue injuries and defects by applying ultrasound to traumatized tissue, it has been demonstrated that the traumatized tissue heals at a faster rate if the acoustic signal envelope of the applied ultrasonic waves is slowly modulated or perturbed. Modulating the signal envelope of the applied ultrasonic waves can be accomplished by either modulating the envelope of the electrical signal to the ultrasound transducer or by modulating the ultrasonic waves in the body by utilizing controlled electromagnetic induced forces.

It has also been demonstrated that in the case of a non-union injury, i.e., where a bone fracture fails to heal, that electromagnetic-stimulation (E-stim) treatment of the non-union injury produces a therapeutic response in bone tissue. E-stim generally uses at least an external coil to produce a therapeutic pulsed uniform, electromagnetic field at the fracture site. For example, a pair of Helmholtz coils can produce a constant uniform field at the fracture or wound sites, above the local magnetic field in tissue.

It is generally believed that E-stim promotes and accelerates the healing of non-union injuries due to the creation of a magnetic flux density which causes the creation and movement of ionic charges within the bone tissue. Bone tissue is mainly an ionic-fluid-saturated porous medium having various ions in the intercellular and interstitial fluid such as potassium ions, sodium ions, magnesium ions, chloride ions, phosphate ions, carbonate ions, bicarbonate ions and those formed by the dissociation of amino acids, proteins, sugars, nucleotides and enzymes. The application of a pulsed electromagnetic field, i.e., the controlled combination of electrostatic and magnetic forces, causes these ions to be charged and moved in a particular direction. The ions diffuse within cells at the treatment area, thereby accelerating the healing process.

According to the present disclosure, the healing of tissue, especially non-union injuries, can be further accelerated by combining ultrasound and E-stim. The forces produced by the applied electromagnetic field add a fluctuating or perturbing force, such as a low frequency modulation force, to the propagating ultrasonic or pressure wave to further stimulate the cells at the treatment area and enhance cellular permeability and ionic diffusion. The largest effect on the acoustic field by the electromagnetic field occurs when the direction of the longitudinal waves is perpendicular to the electromagnetic field, or if the transverse (shear) waves are traveling along the magnetic field lines. The electromagnetic field tends to increase the phase velocity of the ultrasonic waves. The associated magnetic force may be held constant or modulated at a low frequency rate.

SUMMARY OF THE INVENTION

The present invention provides a combined ultrasonic and E-stim treatment apparatus for therapeutically treating traumatic tissue injuries, especially

non-union bone fractures, using combined ultrasound and E-stim. The apparatus includes an ergonomically constructed placement module configured for mounting at least one hybrid ultrasonic transducer assembly having an integral signal generator which provides excitation signals to at least one ultrasonic transducer within the placement module for generating an acoustic field. The placement module further includes at least one electromagnetic coil assembly having at least one electromagnetic coil in proximity to each ultrasonic transducer for generating an electromagnetic field. It is contemplated that timing control circuitry as well as monitoring circuitry for the proper control and operation of the components within the placement module are housed within a main operating unit which may be fit within a pouch worn by the patient or integrally contained in the transducer.

In operation, the placement module is positioned adjacent a part of the patient's body such that the at least one ultrasonic transducer is sonically coupled in position adjacent traumatized tissue and/or an osteochondrial injury. The at least one ultrasonic transducer and at least one electromagnetic coil are then excited by providing an induced signal to these components. The induced signal causes the at least one ultrasonic transducer to impinge ultrasonic pressure waves against the traumatized tissue and/or injury and for the at least one electromagnetic coil to create an electromagnetic field having a magnetic flux density. The frequency of the induced signal can be varied from 1 Hz to 10,000 Hz. The magnetic flux density adds a fluctuating force to the propagating pressure wave in the body to increase the stimulation of the cells in the vicinity of the injury and to enhance cellular permeability which results in an increase in the diffusion of ions into the cells, such as calcium ions in the case of a non-union bone fracture, resulting in increased protein synthesis. An increase in protein synthesis accelerates bone fracture healing and tissue repair. Additionally, it is contemplated to control the average magnetic flux

density, pulse repetition rate, and pulse width of the induced signal for optimal osteogenic stimulation.

Preferably, the main operating unit has an internal power source for powering the signal generator of the ultrasonic transducer assembly, a display for displaying treatment sequence data, a keypad coupled to the signal generator for permitting user operation and/or entry of data. The signal generator includes circuitry having a processor, means for generating a pulsed control signal, and a switch coupled to the processor for regulating the pulsed control signal. The main operating unit further has an alarm for indicating to the user that the treatment time has expired. The alarm is coupled to the processor such that when ultrasonic and E-stim treatment is completed the processor activates the alarm and terminates the induced signal to the components within the placement module.

The present invention also provides a kit for combined ultrasonic and E-stim treatment of traumatized tissue and osteochondrial injuries. The kit includes an ultrasonic transducer assembly having an ultrasonic transducer and signal generator circuitry, an electromagnetic coil assembly having an electromagnetic coil and operating circuitry, a placement module configured for placement therein of the ultrasonic transducer and electromagnetic coil assemblies, and a main operating unit (MOU) or controller coupled to the placement module via a cable. The MOU has an internal power source thereby providing patient mobility. A MOU envisioned for use with the present invention is described in U.S. Patent No. 5,556,372 to Talish et al. which is hereby incorporated by reference.

The present invention further provides a method for combined ultrasonic and E-stim treatment of traumatized tissue and/or osteochondrial injuries. The method entails the steps of locating the site of the injury; positioning a placement module containing at least one ultrasonic transducer assembly and at least one

electromagnetic coil assembly adjacent to the injury such that the at least one ultrasonic transducer and at least one electromagnetic coil of the at least one ultrasonic transducer and at least one electromagnetic coil assemblies, respectively, are in proximity to the injury; activating the at least one ultrasonic transducer and the at least one electromagnetic coil for simultaneously propagating at least one ultrasonic pressure wave towards the injury and creating an electromagnetic field for adding a fluctuating force to the propagating pressure wave.

In an alternative embodiment, a placement module is provided for securing a plurality of ultrasonic transducers and a plurality of electromagnetic coils thereto in a plurality of configurations. The placement module is then secured in proximity to traumatized tissue and/or an osteochondrial injury to provide ultrasonic and E-stim treatment.

BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention are described below with reference to the drawings, which are described as follows:

FIG. 1 is a perspective view of a patient wearing a portable ultrasonic and E-stim treatment apparatus of a first embodiment according to the present invention having a main operating unit or controller and a placement module;

FIG. 2 is a perspective view of an insert secured in a cast ready to receive a combined ultrasound and E-stim transducer head of a portable ultrasonic and E-stim treatment apparatus of a first embodiment;

FIG. 3 is a perspective view of the transducer head of FIG. 2 fully mounted to the cast;

FIG. 4 is a perspective view of another embodiment of a combined ultrasound and E-stim transducer head having a cover with locking structure;

FIG. 5A is a top view of the placement module of FIG. 2 illustrating the size and position of an ultrasonic transducer in relation to the size and position of an electromagnetic coil within the placement module;

FIG. 5B is a cross-sectional view of the placement module of FIG. 2;

FIG. 6A is a top view of a placement module of a portable ultrasonic and E-stim treatment apparatus of another embodiment illustrating the size and position of an ultrasonic transducer in relation to the size and position of an electromagnetic coil within the placement module;

FIG. 6B is a cross-sectional view of the placement module of FIG. 6A;

FIG. 7A is a top phantom view of a placement module of a portable ultrasonic and E-stim treatment apparatus of another embodiment illustrating the size and position of an ultrasonic transducer in relation to the size and position of an electromagnetic coil within the placement module;

FIG. 7B is a cross-sectional view of the placement module of FIG. 7A;

FIG. 8 is a cross-sectional view of a placement module of a portable ultrasonic and E-stim treatment apparatus of another embodiment illustrating the position of an ultrasonic transducer in relation to the position of a cross-shaped electromagnetic coil within the placement module;

FIG. 9 is a cross-sectional view of a placement module of a portable ultrasonic and E-stim treatment apparatus of another embodiment illustrating the position of an ultrasonic transducer in relation to the position of a cross-shaped electromagnetic coil within the placement module;

FIG. 10 is a cross-sectional view of a placement module of a portable ultrasonic and E-stim treatment apparatus of another embodiment illustrating the position of an ultrasonic transducer in relation to the position of a star-shaped electromagnetic coil within the placement module;

FIG. 11A is a top view of a placement module of a portable ultrasonic and E-stim treatment apparatus of another embodiment illustrating the size and position of an ultrasonic transducer in relation to the size and position of an electromagnetic coil within the placement module;

FIG. 11B is a cross-sectional view of the placement module of FIG. 11A;

FIG. 12A is a top view of a placement module of a portable ultrasonic and E-stim treatment apparatus of a further embodiment illustrating the size and position of an ultrasonic transducer in relation to the size and position of an electromagnetic coil within the placement module;

FIG. 12B is a cross-sectional view of the placement module of FIG. 12A;

FIG. 13A is a top phantom view of a placement module of a portable ultrasonic and E-stim treatment apparatus of another embodiment illustrating the size and position of an ultrasonic transducer in relation to the size and position of an electromagnetic coil within the placement module;

FIG. 13B is a first cross-sectional view of the placement module of FIG. 13A;

FIG. 13C is a second cross-sectional view of the placement module of FIG. 13A;

FIG. 14A is a top view of a placement module of a portable ultrasonic and E-stim treatment apparatus of another embodiment illustrating the size and position of an ultrasonic transducer in relation to the size and position of an electromagnetic coil within the placement module;

FIG. 14B is a cross-sectional view of the placement module of FIG. 14A;

FIG. 15A is a top view of a placement module of a portable ultrasonic and E-stim treatment apparatus of yet another embodiment illustrating the size and position of an ultrasonic transducer in relation to the size and position of an electromagnetic coil within the placement module;

FIG. 15B is a cross-sectional view of the placement module of FIG. 15A;

FIG. 16A is a top view of a placement module of a portable ultrasonic and E-stim treatment apparatus of another embodiment having a plurality of ultrasonic transducers and a plurality of electromagnetic coils; and

FIG. 16B is a cross-sectional view of the placement module of FIG. 16A.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Preferred embodiments of the present invention will be described in detail with reference to the attached drawings. Like reference numerals denote the same or similar components in the drawings.

The ultrasonic and E-stim treatment apparatus and methods of the present invention are used for the surgically non-invasive application of ultra high-frequency acoustic energy and magnetic flux density in the treatment of traumatized tissue and/or osteochondrial injuries. Even though this detailed description discusses the treatment of traumatized tissue and/or osteochondrial injuries, the ultrasound and E-stim treatment apparatus can be used to treat osteochondrial defects caused by e.g., medication, infection or metabolic processes.

A. Background Information Relating to the Embodiments Described Herein

1. Pulsed Low Intensity Ultrasound Excitation

Ultrasound wave propagation in tissue exerts a unidirectional radiation force on all absorbing and reflecting obstacles in its path, even at the microstructural level. Low-intensity ultrasound refers to those power levels that just exceed biological thresholds which trigger or evoke general biological regulatory reactions. Although too low to produce direct measurable biological effects, clinical results have established that low intensity ultrasound is sufficient to invoke biological healing processes.

Since the early sixties, the specific physical and biological mechanisms behind the thereapeutic effectiveness of low intensity ultrasound have been extensively investigated. For spatial average-temporal average (SATA) intensities from 0.1 - 0.5 W/cm^2, it is possible to produce the non-thermal, high stress mechanisms of acoustic streaming and cavitation. In vitro tests on isolated fibroblast cells have shown that the effects of ultrasound on the cells are pressure sensitive, suggesting a stable cavitation mechanism. The resulting bubble oscillations, possibly including acoustic microstreaming, can generate high shear stress on the cell membrane, which can affect the cell's permeability to sodium and calcium ions. The increase in cell permeability may result in an increase in calcium uptake, and increase in protein and DNA synthesis in fibroblasts, and account for the observed activation of macrophages. The production of fibroblasts and macrophages characterizes the normal fracture repair process.

For SATA intensities below 0.1 W/cm^2, stable cavitation and acoustic micro-streaming seem quite unlikely. In vivo test results indicate that a low SATA intensity from 30-50 mW/cm^2 is highly effective in stimulation bone fracture repair. These results support the thesis that ultrasonically-induced mechanical vibrations tend

to increase the permeability of the cell membrane to calcium ions. Preliminary clinical results indicate that the initial result of applying pulsed, low intensity ultrasound to traumatized tissue is to increase blood flow in the local region. It is proposed that the increased vascularity and the micromechanical fluid pressure appears to produce an increase in cellular calcium uptake, resulting in increased protein synthesis, thereby accelerating bone fracture healing and tissue repair.

2. Significance of Ultrasound Modulation to Stimulate Vascularity

Test results have shown that there is an increase in vascularity produced with the application of ultrasound to traumatized tissue. In treating bone fractures, the increase in blood flow to the callus, for example, may prove significant in accelerating bone healing. The test results referred to were obtained with an acoustic longitudinal wave and a constant (0 Hz) modulation envelope. It was clearly established that bone healing initially occurs in the periosteal region, followed by healing within the fracture itself (endosteal healing). The increased vascular flow due to ultrasound stimulation occurred in the region of the periosteum. It is proposed that the acoustic wave stimulates the exposed nerve endings of the periosteum, thereby stimulating local vascularization. The acoustic wave is preferably a constant envelope sine wave at a carrier frequency of 1.5 MHZ and a repetition frequency of 1.0 kHz.

A slowly modulated acoustic signal envelope, at a rate less than 100 Hz, may prove to be more osteogenic, both in the fracture gap and on the periosteum. It has been demonstrated that the micromechanical stimuli (0.5 Hz for 17 minutes, daily) significantly improves the healing of tibial fractures. This accelerated healing process has been correlated with the promotion of fracture revascularization. The modulation of the excitation may be accomplished by either modulating the envelope

of the electrical signal to the ultrasound transducer or by modulating the pressure wave in the body, utilizing controlled electromagnetic induced forces.

3. Low Frequency Electromagnetic Excitation

In cases where the fracture fails to heal, referred to as a non-union, the most common treatment is surgery or electromagnetic-stimulation (E-stim). As discussed above, E-stim uses an external coil to produce a therapeutic pulsed electromagnetic field at the fracture site.

4. Combined Ultrasonic and Electromagnetic Stimulation

Specifically, the combined ultrasonic and E-stim treatment methods and apparatus of the present invention generate and control the spatial distribution of a non-uniform, time-varying, directionally-oriented electromagnetic field to produce an ionic current and electric voltage, relative to the spatial and temporal generation and control of a time-varying, directionally-oriented non-uniform acoustic pressure wave, in living tissue. The main physical factors that characterize ultrasound propagation in tissue are mechanical, affecting the particle displacement, velocity, acceleration, and pressure at the microstructural level.

In preferred embodiments of the present invention, the forces produced by the applied electromagnetic field are employed to add a perturbing or fluctuating force, such as a low frequency modulation force, to the propagating pressure wave in the body to increase the stimulation of the cells in the vicinity of the injury and to enhance cellular permeability which results in an increase in the diffusion of ions into the cells, such as calcium ions in the case of a non-union bone fraeture, resulting in increased protein synthesis. As indicated above, an increase in protein synthesis accelerates bone fracture healing and tissue repair.

The low frequency perturbation of the propagating pressure wave can be produced by positioning the electromagnetic coil in a wide variety of orientations relative to the direction of the propagating pressure wave. The largest effect on the pressure wave occurs when the direction of the longitudinal pressure wave is perpendicular to the magnetic field, or if the transverse (shear) waves are traveling along the magnetic field lines. In this case, the magnetic field tends to increase the phase velocity of the sound wave. The associated magnetic force may be held constant or modulated at a low frequency rate by controlling the magnitude of an induced signal to the electromagnetic coil.

Consider the effect of a magnetic field on the propagation of a sound wave in a conducting fluid, such as the soft tissue-bone complex. Bone tissue is mainly an ionic-fluid-saturated porous medium having various ions in the intercellular and interstitial fluid, such as potassium ions, sodium ions, magnesium ions, chloride ions, phosphate ions, carbonate ions, bicarbonate ions and those formed by the dissociation of amino acids, proteins, sugars, nucleotides and enzymes. The movement of charged ions by the controlled combination of electrostatic, magnetic and acoustic radiation forces can promote and accelerate tissue healing. The interrelationships between these physical entities can be depicted by the general acoustic wave equation in a solid, homogeneous medium.

It is well known that the magnetic force F on a positive charge q moving with a velocity v in a magnetic field of flux density B is given by the vector product $F = qv \times B$. The vector product gives the same direction for F as does the classic Fleming's left-hand rule and establishes that F is perpendicular to B. If the longitudinal acoustic waves are propagated in the direction of the magnetic flux, there is no effect on the acoustic field. As indicated above, the largest effect to the acoustic field occurs when the direction of the longitudinal waves is perpendicular to

the magnetic field, or if the transverse (shear) waves are traveling along the magnetic field lines.

In general, the acoustic waves can travel at an arbitrary angle with respect to the magnetic field flux lines. When this occurs, the nature of the resulting acoustic wave will depend markedly on whether the fluid velocity is parallel with or perpendicular to the plane established by k (wavenumber) and B. If the particle velocity is perpendicular to the k-B plane, then the wave motion will be transverse, having a velocity equal to B cos $\theta/\sqrt{\rho}$, where θ is the angle between the direction of propagation and the magnetic field, and ρ is the fluid density. If the particle velocity vector lies in the k-B plane, then the wave mode will contain both a transverse and a longitudinal wave, corresponding to the particle velocity components perpendicular and parallel with k, respectively. It is shown that a density fluctuation is produced only if there is a velocity component in the direction of propagation and the perturbation in the magnetic field is always perpendicular to k.

B. Embodiments of the Present Invention

The various embodiments of the present invention include an ergonomically constructed placement module having a strap or other fastening means for being secured adjacent an injured part of a patient's body. At least one ultrasonic transducer assembly and at least one electromagnetic coil assembly are attached to or housed within the placement module and properly positioned in proximity to the traumatized tissue and/or osteochondrial injury. The at least one ultrasonic transducer assembly includes at least one ultrasonic transducer and the at least one electromagnetic coil assembly includes at least one electromagnetic coil. Different types of ultrasonic transducers and signals can be provided, such as those described and schematically depicted in U.S. Patent No. 5,520,612 to Winder et al. which is

hereby incorporated by reference. Additionally, ultrasonic transducers can be used such as those described and illustrated in U.S. Patent Application Serial No. 09/040,155 filed on March 17, 1998, the contents of which are incorporated herein by reference.

The apparatus preferably uses electromagnetic field coil configurations to produce asymmetric, non-uniform or time-varying fields which can be used for selective spatial stimulation in tissue. In the embodiments described below the frequency of the induced signal to the at least one ultrasonic transducer and at least one electromagnetic coil can be varied from 1 Hz to 10 KHz. It is preferred that for optimal osteogenic stimulation, in the treatment of non-union bone fractures, that the average magnetic flux density, pulse repetition rate, and pulse width of the induced signal be controlled. Precise control of the average magnetic flux implies considering the combined magnetic field of the applied magnetic field via the at least one electromagnetic coil and the local magnetic fields. The latter includes the Earth's magnetic field and the effects of ferromagnetic materials in the vicinity which create additional magnetic flux that flows through tissue.

The apparatus also preferably utilizes a portable, ergonomically constructed main operating unit (MOU) having an internal power source which is worn by the patient. The internal power source provides control signals to the ultrasonic transducers and electromagnetic coils at the placement module. It is preferred that the electromagnetic coils produce time-varying, non-uniform electromagnetic fields. The MOU which is utilized is preferably the one described in U.S. Patent No. 5,556,372 to Talish et al.; the contents of which are incorporated herein by reference. The ultrasonic transducers and associated circuitry preferably used are described in U.S. Application Serial No. 09/040,157; the contents of which are incorporated herein by reference.

Turning to the figures, in particular FIG. 1, a patient wearing a first embodiment of the portable ultrasonic and E-stim treatment apparatus of the present invention is shown. The ultrasonic and E-stim treatment apparatus designated generally by reference numeral 10 includes a MOU 12, a placement module 14, and a cable 16 connecting the MOU 12 with the placement module 14. The MOU 12 is positioned within a pouch or carrying case 18 which is strapped to the patient by a harness 20 to provide mobility to the patient during treatment. The placement module 14 is secured to a mounting assembly 22 having a placement band 24 for placing and securing the placement module 14 in proximity to a treatment area. The placement band 24 is configured to firmly secure the placement module 14 to the patient. A sponge-like material may preferably line the inner surface of the placement band 24 for providing comfort to the patient and to prevent window edema.

Referring to FIGS. 2 and 3, another embodiment of the portable ultrasonic and E-stim treatment apparatus of the present invention is shown. An insert 90 is shown secured within a cast 92 of a patient requiring ultrasound treatment. A tab 94 which is attached at its lower end to a transmission-enhancing medium is shown extending from insert 90. Following the placement of ultrasound transducer head module 96 into insert 90, a cover 98 is placed over the top of the insert 90 and strap 100 is adjusted to secure the entire apparatus in place. The ultrasound transducer head module 96 is similar to the placement module 14 shown in FIG. 1. The ultrasound transducer array can transmit signals designed for therapeutic and/or diagnostic operation. In the diagnostic mode, reflection echo data is processed upon reception for imaging and tissue analysis. As used herein, one means for receiving reflected diagnostic date includes the VS transducer assembly, used circuitry or software in the MOU for processing and/or analyzing the echo returns.

With reference to FIG. 4, another embodiment of the ultrasound and

E- stim treatment apparatus is shown. FIG. 4 illustrates a perspective view of a cover 150 having locking structure. The cover 150 has two locking tabs 154 for locking the cover within an insert. A protrusion 158 is similarly formed on locking tab 154 to engage a groove on the inner surface of an insert. Also shown in FIG. 4 is an ultrasound treatment module with treatment head 160 which is similar to the placement module 14 shown in FIG. 1. Furthermore, a conical helical spring 162 is connected to a lower surface of the cover 150 to bias the treatment head 160 in a direction toward a treatment site.

With reference to FIGS. 5A to 7B, there are shown top and cross-sectional views of the placement module 14 of the embodiments of FIG. 2 (FIGS. 5A and 5B), FIGS. 6A and 6B, and FIGS. 7A and 7B. These embodiments each have an ultrasonic transducer assembly 26 and an electromagnetic coil assembly 28. The ultrasonic transducer assembly 26 includes at least one ultrasonic transducer 30 and related circuitry, including a signal generator (not shown). The electromagnetic coil assembly 28 includes at least one electromagnetic coil 32. The ultrasonic transducer 30 and the electromagnetic coil 32 are positioned differently with respect to each other for each of these embodiments, as described herein below. Further, in these embodiments, the ultrasonic transducer 30 is positioned below the electromagnetic coil 32, i.e., closer to the injury, and has a smaller diameter than the electromagnetic coil 32.

The ultrasonic transducer assembly 26 and electromagnetic coil assembly 28 for these embodiments are coupled to the MOU 12 by cable 16. The cable 16 is preferably a multiconductor cable capable of transmitting relatively low frequency RF or optical signals, as well as digital signals. The cable 16 may include coaxial cable or other types of suitable shielded cable. Alternatively, the cable 16 may include fiber optic cable for transmitting optical signals.

The signals from the MOU 12 may be transmitted continuously or as a series of pulses. It is contemplated that a voltage magnitude of the signals to the ultrasonic transducer 30 be varied to vary a transmission power of the propagated ultrasonic waves. Further, it is contemplated that a voltage magnitude of the signal to the electromagnetic coil 32 be varied to vary the magnetic flux density.

With reference to FIGS. 5A and 5B, the electromagnetic coil 32 is positioned parallel to the ultrasonic transducer 30. In this configuration, the longitudinal acoustic waves are propagated in the same direction as the magnetic flux, and hence this configuration provides the smallest effect on the acoustic field. For example, since the electromagnetic coil 32 is parallel to the horizontal axis, when a current is supplied to the electromagnetic coil 32, the resulting magnetic flux is parallel to the longitudinal axis of the electromagnetic coil 32 according to Maxwell's Equations. Hence, the magnetic flux is in the same direction as the propagating longitudinal acoustic waves.

In FIGS. 6A and 6B, the electromagnetic coil 32 is positioned at an angle θ with respect to the horizontal axis of the placement module 14. In this configuration, the longitudinal acoustic waves are propagated at the same angle θ with respect to the direction of the magnetic flux, and hence this configuration provides a noticeable effect on the acoustic field.

In FIGS. 7A and 7B, the electromagnetic coil 32 is positioned transverse to the ultrasonic transducer 30. In this configuration, the longitudinal acoustic waves are propagated transverse to the direction of the magnetic flux, and hence this configuration provides the largest effect on the acoustic field.

With reference to FIGS. 8 to 10, there are shown cross-sectional views of further embodiments of the present invention. These embodiments each have an ultrasonic transducer assembly 36 and an electromagnetic coil assembly 38 housed

within a placement module 40: The ultrasonic transducer assembly 36 includes an ultrasonic transducer 42 and related circuitry, including a signal generator (not shown). The electromagnetic coil assembly 38 includes a cross-shaped electromagnetic coil 44 or star-shaped electromagnetic coil 46. The ultrasonic transducer 42 and the electromagnetic coils 44 and 46 are positioned differently with respect to each other for each of these embodiments, as described herein below. Further, in these embodiments, the ultrasonic transducer 42 is positioned below the electromagnetic coils 44 and 46, i.e., closer to the injury, and has a larger diameter than the electromagnetic coils 44 and 46. Cross-shaped electromagnetic coil 44 has a first coil 48 and a second coil 50. Star-shaped electromagnetic coil 46 has a first coil 52, a second coil 54, and a third coil 56.

The ultrasonic transducer assembly 36 and electromagnetic coil assembly 38 are coupled to a MOU (not shown) similar to MOU 12 shown in FIG. 1 or MOU 110 shown in FIG. 2 by cable 16. Signals transmitted via the cable 16 to the components within placement module 40 may be transmitted continuously or as a series of pulses.

With reference to FIG. 8, the first and second coils 48 and 50 of the cross-shaped electromagnetic coil 44 are perpendicular to each other and positioned at an acute angle θ with respect to a longitudinal axis of the placement module 40. In this configuration, a magnetic flux is created transverse to first coil 48 and another magnetic flux is created transverse to second coil 50. Since both coils 48 and 50 are perpendicular to each other and at an angle θ with respect to the longitudinal axis of the placement module 40, the longitudinal acoustic waves propagated by the ultrasonic transducer 42 are modulated or perturbed by a first magnetic flux created by the first coil 48 and a second magnetic flux created by the second coil 50. It is believed that modulation of the acoustic waves by the first and second magnetic fluxes stimulates

and enhances cellular permeability and the diffusion of ions within the traumatized tissue or osteochondrial injury to accelerate healing thereof as discussed above.

In FIG. 9, the first and second coils 48 and 50 of the cross-shaped electromagnetic coil 44 are perpendicular to each other, but positioned at a right angle θ with respect to a longitudinal axis of the placement module 40. In this configuration, a magnetic flux is created transverse to first coil 48 and another magnetic flux is created transverse to second coil 50. Since both coils 48 and 50 are perpendicular to each other and at a right angle θ with respect to the longitudinal axis of the placement module 40, the longitudinal acoustic waves propagated by the ultrasonic transducer 42 are slightly modulated or perturbed by a first magnetic flux created by the first coil 48 and greatly modulated by a second magnetic flux created by the second coil 50. Accordingly, by changing the position of the electromagnetic coil assembly 44 within the placement module 40, the amount of modulation of the acoustic waves can be controlled for optimal osteogenic stimulation. It is contemplated to provide different circuitry for driving the first coil 48 and the second coil 50 to alternate between the creation of the first magnetic flux and the second magnetic flux during ultrasonic and E-stim treatment using the apparatus.

As shown in FIG. 10, the first, second and third coils 52, 54 and 56 of the star-shaped electromagnetic coil 46 are positioned at an acute angle θ with respect to each other and at the same angle θ with respect to a longitudinal axis of the placement module 40 if one of the coils 52, 54 and 56 is perpendicular to the longitudinal axis. In this configuration, a first magnetic flux is created transverse to the first coil 52, a second magnetic flux is created transverse to the second coil 54, and a third magnetic flux is created transverse to the third coil 56. By controlling the orientation of the three coils 52, 54 and 56, the direction of the first, second and third

magnetic fluxes can be controlled to vary the amount of modulation of the acoustic waves propagated by the ultrasonic transducer 42.

With reference to FIGS. 11A to 15B, there are shown various top and cross-sectional views of variations of placement module 60. All of these variations have an ultrasonic transducer assembly 26 and an electromagnetic coil assembly 28. The ultrasonic transducer assembly 26 includes an ultrasonic transducer 30 and related circuitry, including a signal generator (not shown). The electromagnetic coil assembly 28 includes an electromagnetic coil 32. The ultrasonic transducer 30 and the electromagnetic coil 32 are positioned differently with respect to each other for each of the variations illustrated by FIGS. 11A to 15B, as described herein below. Further, in the variations illustrated by FIGS. 11A to 15B, the ultrasonic transducer 30 is positioned below the electromagnetic coil 32, i.e., closer to the injury.

The electromagnetic coil assembly 28 and the ultrasonic transducer assembly 26 are individually coupled by cables 62 and 64, respectively, to a MOU (not shown). The MOU can be similar to MOU 12 of the embodiment shown in FIG. 1 or MOU 110 of the embodiment shown in FIG. 2. The cables 62 and 64 are preferably multiconductor cables capable of transmitting relatively low frequency RF or optical signals, as well as digital signals. The cables 62 and 64 may include coaxial cable or other types of suitable shielded cable. Alternatively, the cables 62 and 64 may include fiber optic cable for transmitting optical signals. The signals may be transmitted continuously or as a series of pulses. Additionally, with respect to these embodiments, the signals may be transmitted at different times and at varying periods for driving the ultrasonic transducer and electromagnetic coil assemblies at different times with respect to each other, since the assemblies are not powered by the same cable as in other embodiments.

With reference to FIGS. 11A and 11B, the electromagnetic coil 32 is positioned in a housing 66 which is positioned on top of the placement module 60. The electromagnetic coil 32 is parallel to the ultrasonic transducer 30 within the placement module 60. In this configuration, the longitudinal acoustic waves are propagated in the same direction as the magnetic flux, and hence this configuration provides the smallest effect on the acoustic field. For example, since the electromagnetic coil 32 is parallel to the horizontal axis, when a current is supplied to the electromagnetic coil 32, the resulting magnetic flux is parallel to the longitudinal axis of the electromagnetic coil 32 according to Maxwell's Equations. Hence, the magnetic flux is in the same direction as the propagating longitudinal acoustic waves.

In FIGS. 12A and 12B, the electromagnetic coil 32 is positioned within the housing 66 and at an angle θ with respect to the horizontal axis of the placement module 60. In this configuration, the longitudinal acoustic waves are propagated at the same angle θ with respect to the direction of the magnetic flux, and hence this configuration provides a noticeable effect on the acoustic field.

In FIGS. 13A to 13C, the electromagnetic coil 32 is positioned within the housing 66 and transverse to the ultrasonic transducer 30. In this configuration, the longitudinal acoustic waves are propagated transverse to the direction of the magnetic flux, and hence this configuration provides the largest effect on the acoustic field.

FIGS. 14A and 14B show the electromagnetic coil 32 wrapped around the placement module 60. The electromagnetic coil 32 is wrapped parallel to the ultrasonic transducer 30 within the placement module 60. In this configuration, the longitudinal acoustic waves are propagated in the same direction as the magnetic flux, and hence this configuration provides the smallest effect on the acoustic field. For example, since the electromagnetic coil 32 is parallel to the horizontal axis, when a

current is supplied to the electromagnetic coil 32, the resulting magnetic flux is parallel to the longitudinal axis of the electromagnetic coil 32 according to Maxwell's Equations. Hence, the magnetic flux is in the same direction as the propagating longitudinal acoustic waves.

In FIGS. 15A and 15B, the electromagnetic coil 32 is wrapped around the housing 66 at an angle θ with respect to the horizontal axis of the placement module 60. In this configuration, the longitudinal acoustic waves are propagated at the same angle θ with respect to the direction of the magnetic flux, and hence this configuration provides a noticeable effect on the acoustic field.

FIGS. 16A and 16B show two placement modules 70, similar to placement module 14 of FIG. 2, attached to a placement band 72. The placement modules 70 each house an ultrasonic transducer assembly 74 having an ultrasonic transducer 76 and an electromagnetic coil assembly 78 having an electromagnetic coil 80. An additional electromagnetic coil assembly 78 is positioned between the two placement modules 70. This arrangement is particularly advantageous in spinal repair and intervertebral fusion procedures wherein ultrasound and electromagnetic energy is focused at the site. The two placement modules 70 and the additional electromagnetic coil assembly 82 are positioned at an angle θ with respect to each other and are powered by respective cables 84, 86 and 88, respectively, connected to an MOU (not shown) similar to MOU 12 or MOU 110. It is contemplated that the placement band 72 be manufactured from a flexible material to enable the placement band 72 to be positioned in a plurality of configurations.

In operation the placement band 72 is affixed in proximity to the traumatized tissue or osteochondrial injury. The ultrasonic transducers 76 and the electromagnetic coils 80 are then activated for a predetermined amount of time to impinge modulated acoustic waves at the injury site. It is contemplated that the

electromagnetic coils 80 can be positioned in a variety of positions to control the amount of modulation as discussed above with reference to several embodiments. It is further contemplated to individually drive the ultrasonic transducers 76 and the electromagnetic coils 80 at different times and at varying periods.

It is additionally contemplated to construct the placement band 72 from suitable conductive plastics, such as conductive ABS plastics with either carbon, stainless steel, nickel or aluminum fibers to forego the use of wires for connecting each ultrasonic transducer and electromagnetic coil assembly to a specific cable. In such an embodiment, the conductive placement band would be used to electrically connect the ultrasonic transducer and electromagnetic coil assemblies to an MOU via a single cable.

It is also contemplated to provide each of the embodiments of the present invention as a kit for combined ultrasonic and E-stim treatment of traumatized tissue and osteochondrial injuries. The kit can include the ultrasonic transducer assembly having the ultrasonic transducer and signal generator circuitry, the electromagnetic coil assembly having the electromagnetic coil and operating circuitry, the placement module configured for placement therein of the ultrasonic transducer and electromagnetic coil assemblies, and the main operating unit (MOU) coupled to the placement module.

For all the embodiments disclosed herein, it is contemplated that an ultrasound conducting gel be positioned between the placement modules of the embodiments herein and the injured part of the patient's body to prevent attenuation of the ultrasonic waves. It is also contemplated that one or more transducers can be converted to receive reflected diagnostic data from the treatment site. This permits real time evaluation of the injury site and healing process.

Block diagrams of first and second preferred embodiments of the ultrasonic transducer assembly circuitry is shown by FIGS. 6 and 6A in U.S. Patent No. 5,556,372, the contents of which are incorporated herein by reference.

It will be understood that various modifications can be made to the various embodiments of the present invention herein disclosed without departing from its spirit and scope. For example, various modifications may be made in the structural configuration of the placement modules and the configuration of the ultrasonic transducer and electromagnetic coil assemblies. Therefore, the above description should not be construed as limiting the invention but merely as presenting preferred embodiments of the invention. Those skilled in the art will envision other modifications within the scope and spirit of the present invention as defined by the claims presented below.

WHAT IS CLAIMED IS:

1. A treatment assembly for providing ultrasonic and electromagnetic stimulation to a treatment area, said assembly comprising:

at least one ultrasonic transducer assembly having at least one ultrasonic transducer;

at least one electromagnetic coil assembly having at least one electromagnetic coil operatively associated with said at least one ultrasonic transducer assembly;

a placement module configured to be worn by a patient, said placement module being configured to receive said at least one ultrasonic transducer assembly and said at least one electromagnetic coil assembly such that when said placement module is worn said at least one ultrasonic transducer and said at least one electromagnetic coil are positioned to focus energy toward said treatment area; and

a main operating unit for providing at least one driving signal to said at least one ultrasonic transducer assembly for driving said at least one ultrasonic transducer and said at least one electromagnetic coil to provide ultrasonic and electromagnetic stimulation to said treatment area.

2. The treatment assembly according to claim 1, wherein said main operating unit is coupled to said at least one ultrasonic transducer assembly by a first cable and said at least one electromagnetic coil assembly by a second cable for providing said at least one driving signal to the at least one ultrasonic transducer assembly and said at least one electromagnetic coil assembly at different times and at varying periods.

3. The treatment assembly according to claim 1, wherein said at least one electromagnetic coil is positioned at an angle θ with respect to a horizontal axis of said at least one ultrasonic transducer, where θ is greater than or equal to zero degrees and less than or equal to 90 degrees.

4. The treatment assembly according to claim 1, wherein said at least one electromagnetic coil is wrapped around said placement module.

5. The treatment assembly according to claim 1, wherein said at least one ultrasonic transducer is positioned closer to said treatment area than said at least one electromagnetic coil when said placement module is positioned in proximity to said treatment area.

6. The treatment assembly according to claim 1, wherein said placement module is constructed from a conductive material and said at least one ultrasonic transducer and said at least one electromagnetic coil are electrically coupled to said main operating unit via said conductive material.

7. The treatment assembly according to claim 1, wherein said at least one ultrasonic transducer includes means for receiving reflected diagnostic data.

8. The treatment assembly according to claim 1, wherein said at least one electromagnetic coil provides a non-uniform electromagnetic field.

9. A method for ultrasonically and electromagnetically treating tissue, said method comprising the steps of:

providing a main operating unit having an internal power source coupled to at least one ultrasonic transducer assembly and at least one electromagnetic coil assembly, said at least one ultrasonic transducer assembly includes at least one ultrasonic transducer, said at least one electromagnetic coil assembly includes at least one electromagnetic coil;

providing a placement module configured to receive said at least one ultrasonic transducer assembly and said at least one electromagnetic coil assembly such that when said placement module is secured to a patient's body said at least one ultrasonic transducer and said at least one electromagnetic coil are positioned to focus energy toward said treatment area;

exciting said at least one ultrasonic transducer to impinge ultrasonic waves towards the treatment area; and

exciting said at least one electromagnetic coil to create an electromagnetic field.

10. The method according to claim 9, wherein said steps of exciting said at least one ultrasonic transducer and said at least one electromagnetic coil are performed simultaneously by transmitting a control signal from said main operating unit.

11. The method according to claim 9, wherein said steps of exciting said at least one ultrasonic transducer and said at least one electromagnetic coil are performed independently by transmitting from said main operating unit at least a first control signal to excite said at least one ultrasonic transducer to propagate ultrasonic waves and by transmitting at least a second control signal to excite said at least one electromagnetic coil to generate magnetic field lines.

12. The method according to claim 11, further comprising the step of varying a magnitude of said first control signal to vary a transmission power of said propagated ultrasonic waves.

13. The method according to claim 11, further comprising the step of varying a magnitude of said second control signal to vary a magnetic level of the magnetic field lines.

14. The method according to claim 9, further comprising the step of orienting said at least one electromagnetic coil at an angle θ with respect to a horizontal axis of said at least one ultrasonic transducer.

15. The method according to claim 14, wherein θ is greater than or equal to zero degrees and less than or equal to 90 degrees.

16. The method according to claim 9, further including the step of receiving reflected diagnostic data by said at least one ultrasonic transducer.

17. The method according to claim 9, further comprising the step of securing said main operating unit within a carrying case for providing patient mobility during treatment.

18. The method according to claim 9, wherein said step of exciting said at least one electromagnetic coil creates a non-uniform electromagnetic field.

19. A method for ultrasonically and electromagnetically treating tissue, said method comprising the steps of:

securing at least one ultrasonic transducer to a placement band;

securing at least one electromagnetic coil to said placement band;

affixing the placement band on a patient such that said at least one ultrasonic transducer is in proximity to said treatment area;

exciting said at least one ultrasonic transducer to impinge ultrasonic waves towards said treatment area; and

exciting said at least one electromagnetic coil to create a modulating force to modulate said ultrasonic waves.

20. The method according to claim 19, further comprising the step of connecting said at least one ultrasonic transducer and said at least one electromagnetic coil to an operating unit, said operating unit having an internal power source.

21. The method according to claim 19, further including the step of receiving reflected diagnostic data by said at least one ultrasonic transducer.

22. The method according to claim 19, further comprising the step of orienting said at least one electromagnetic coil at an angle θ with respect to a horizontal axis of said at least one ultrasonic transducer, where θ is greater than or equal to zero degrees and less than or equal to 90 degrees.

23. The method according to claim 17, wherein said step of exciting said at least one electromagnetic coil creates a non-uniform modulating force.

24. An apparatus for providing ultrasonic and electromagnetic stimulation to a treatment area, said apparatus comprising:

means for propagating a pressure wave towards said treatment area;

means for generating an electromagnetic field to modulate said pressure wave; and

control means for controlling the means for generating to vary the amount of modulation of said pressure wave and for activating said means for propagating and said means for generating at respective times.

25. The apparatus according to claim 24, wherein said means for generating generates a non-uniform electromagnetic field.

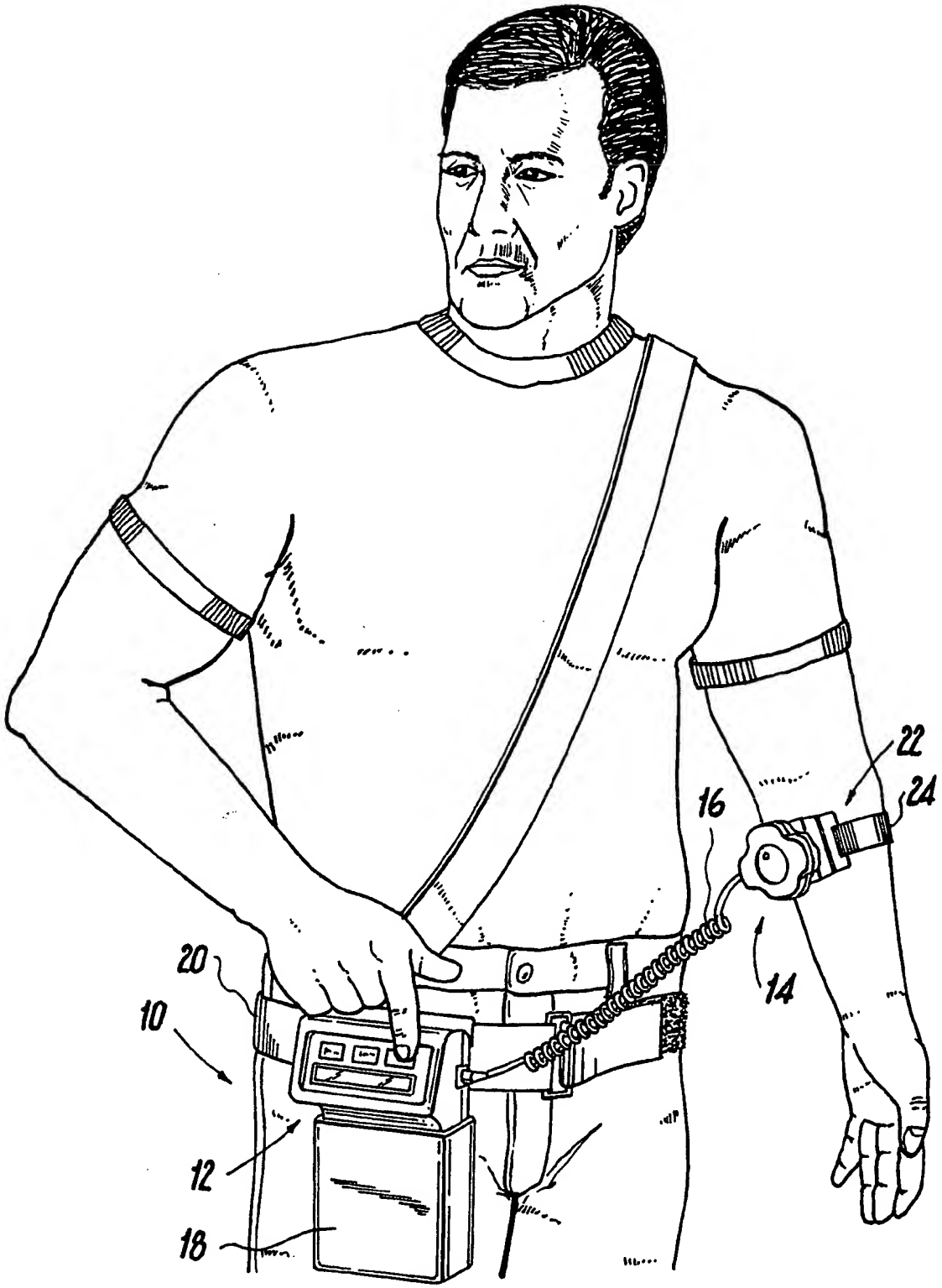


Fig. 1

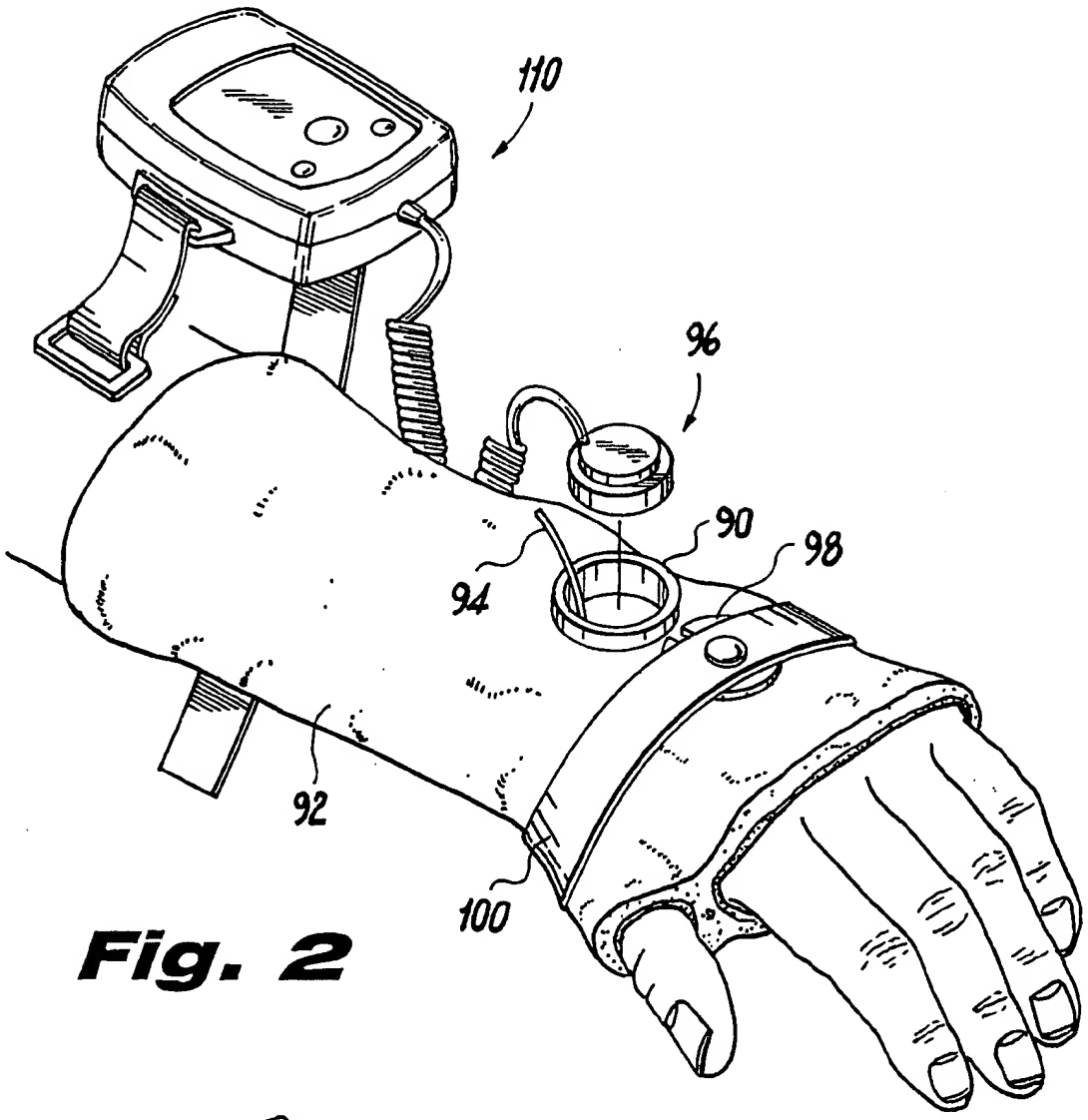


Fig. 2

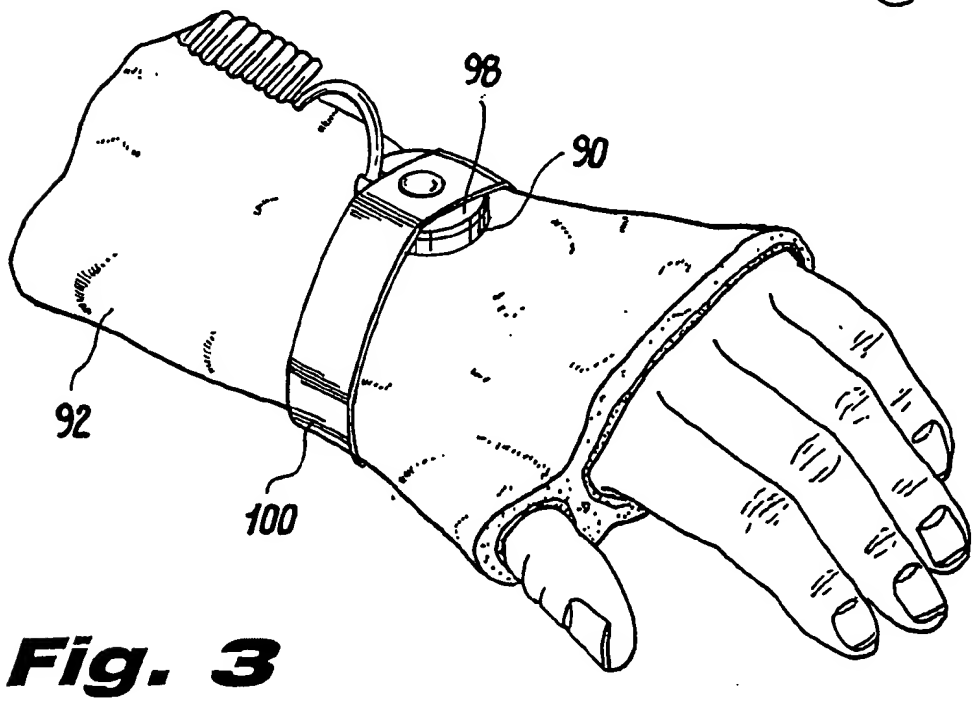
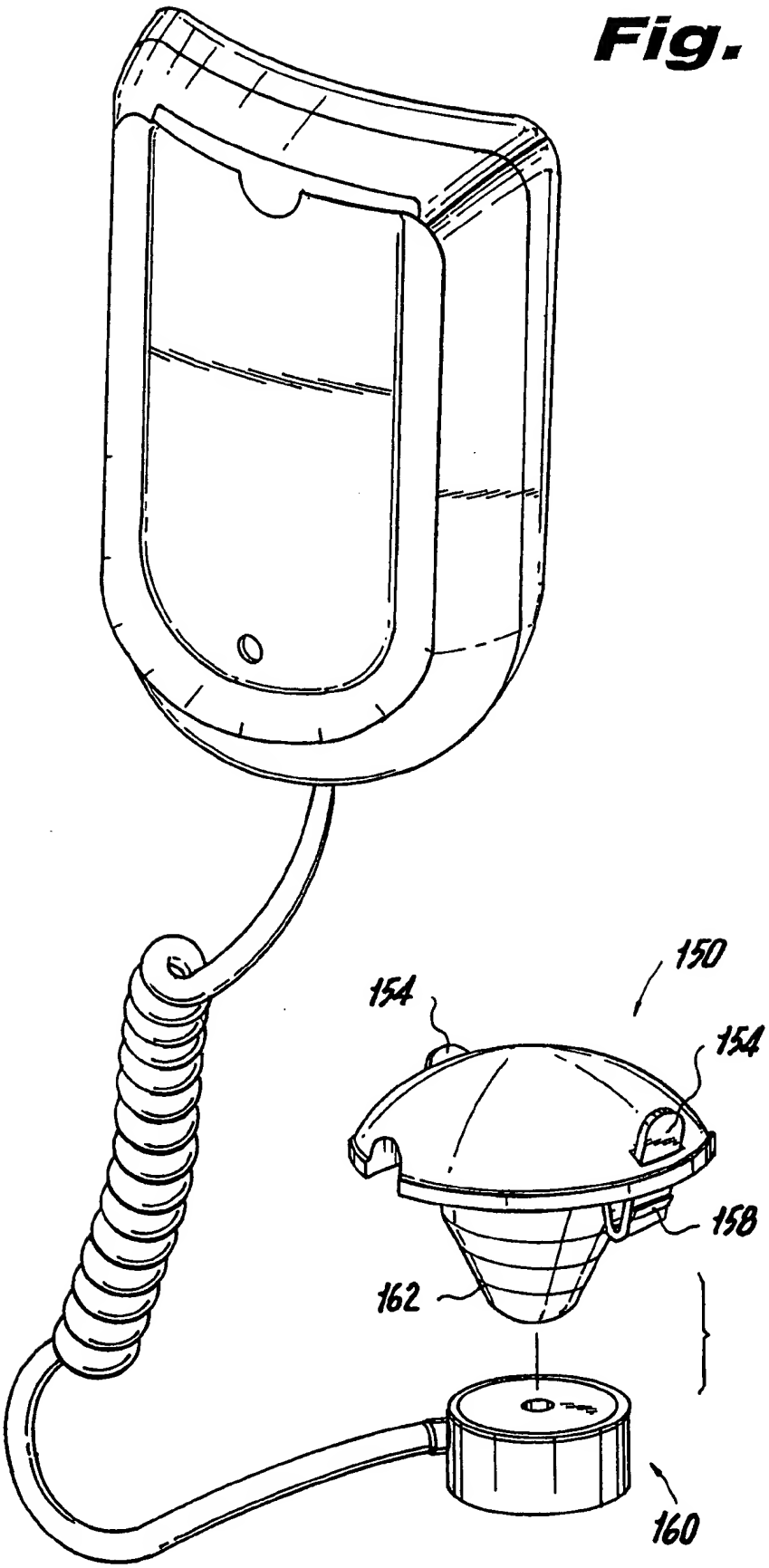


Fig. 3

Fig. 4



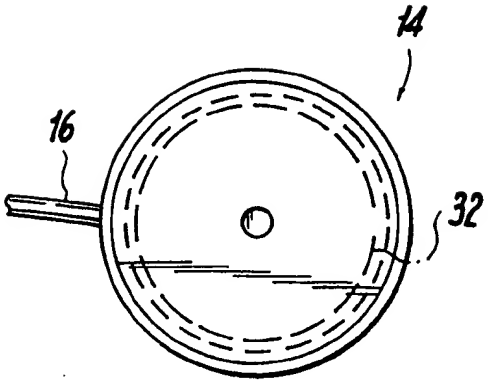


Fig. 5A

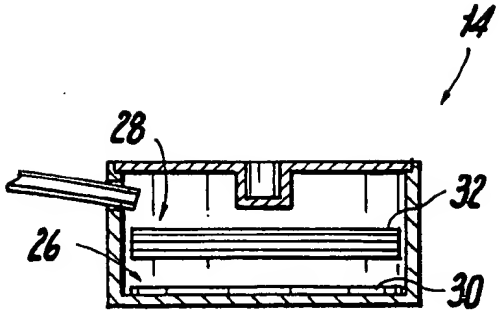


Fig. 5B

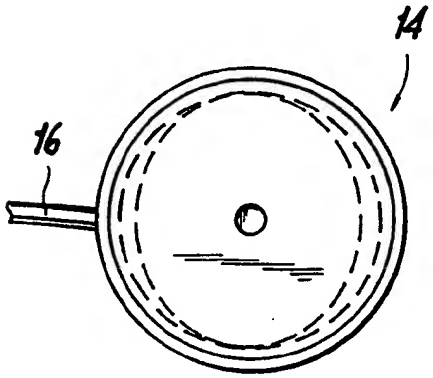


Fig. 6A

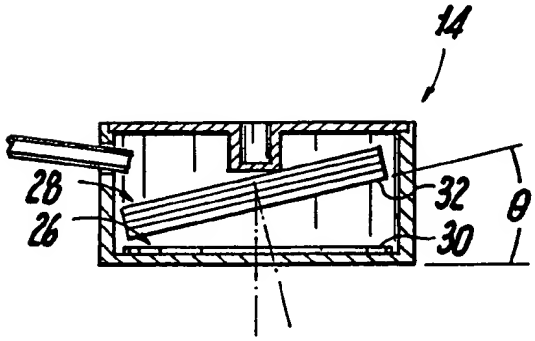


Fig. 6B

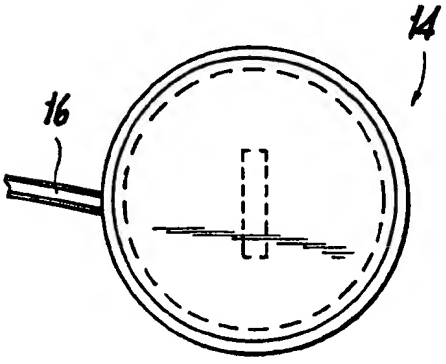


Fig. 7A

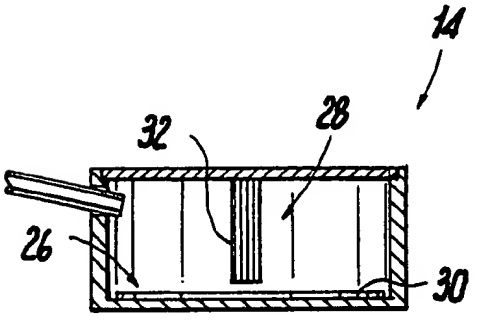


Fig. 7B

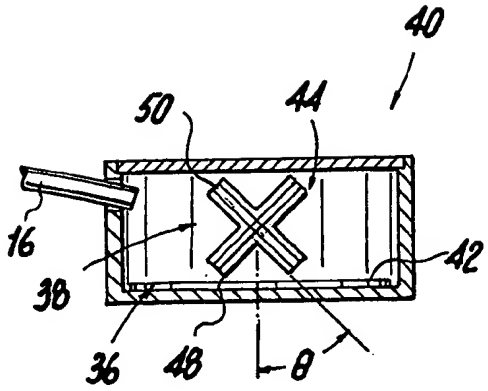


Fig. 8

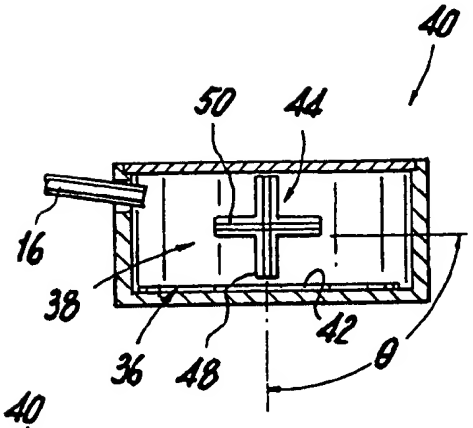


Fig. 9

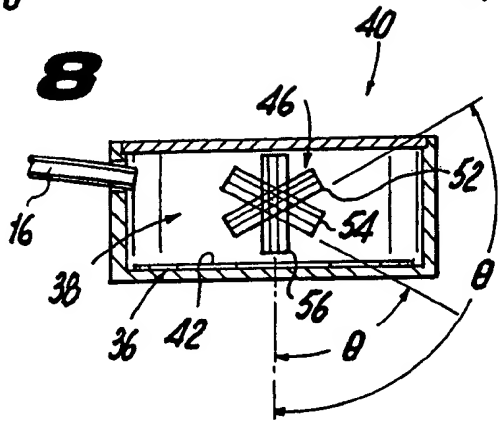


Fig. 10

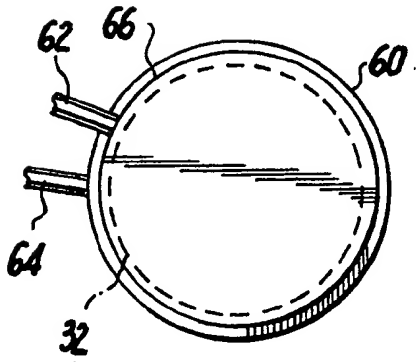


Fig. 11A

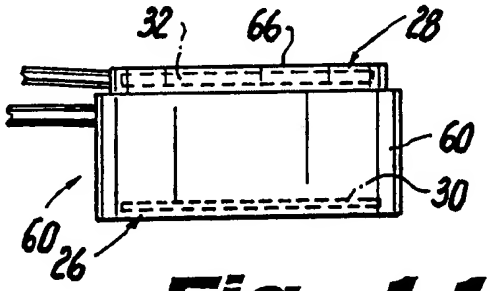


Fig. 11B

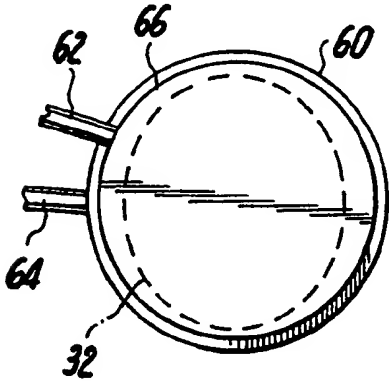


Fig. 12A

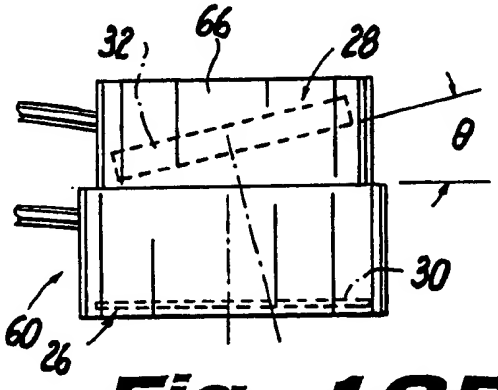


Fig. 12B

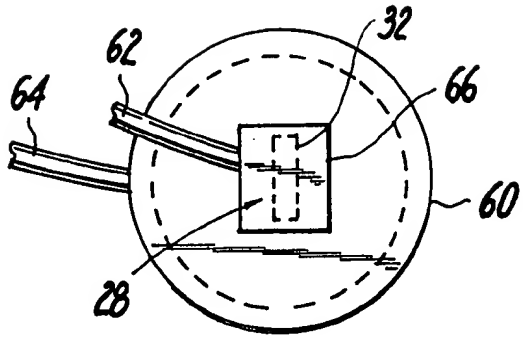


Fig. 13A

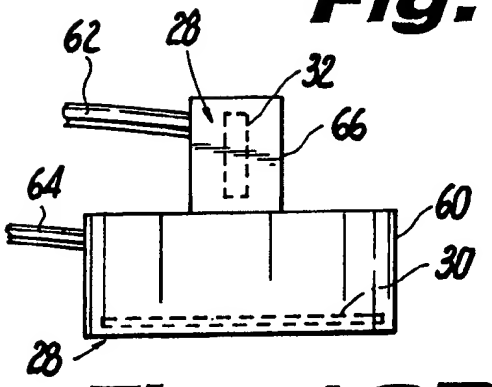


Fig. 13B

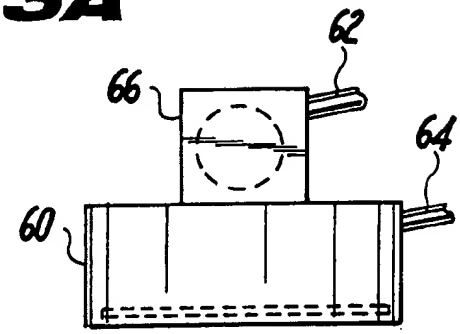


Fig. 13C

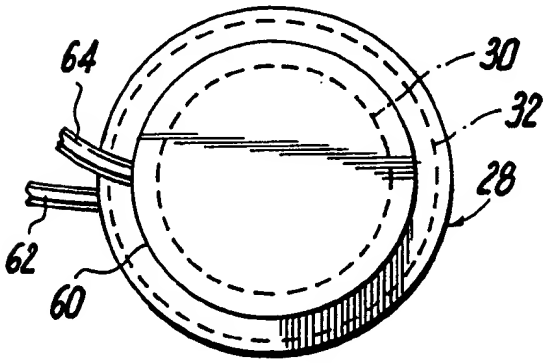


Fig. 14A

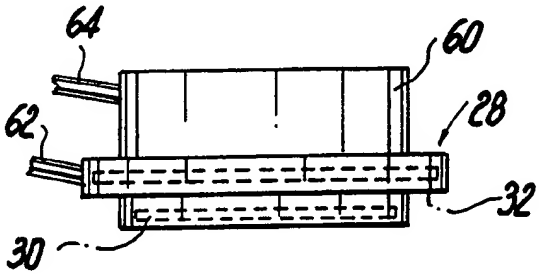


Fig. 14B

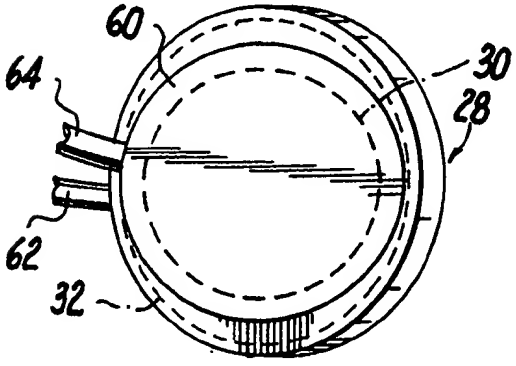


Fig. 15A

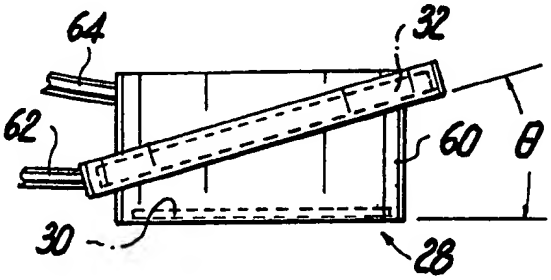


Fig. 15B

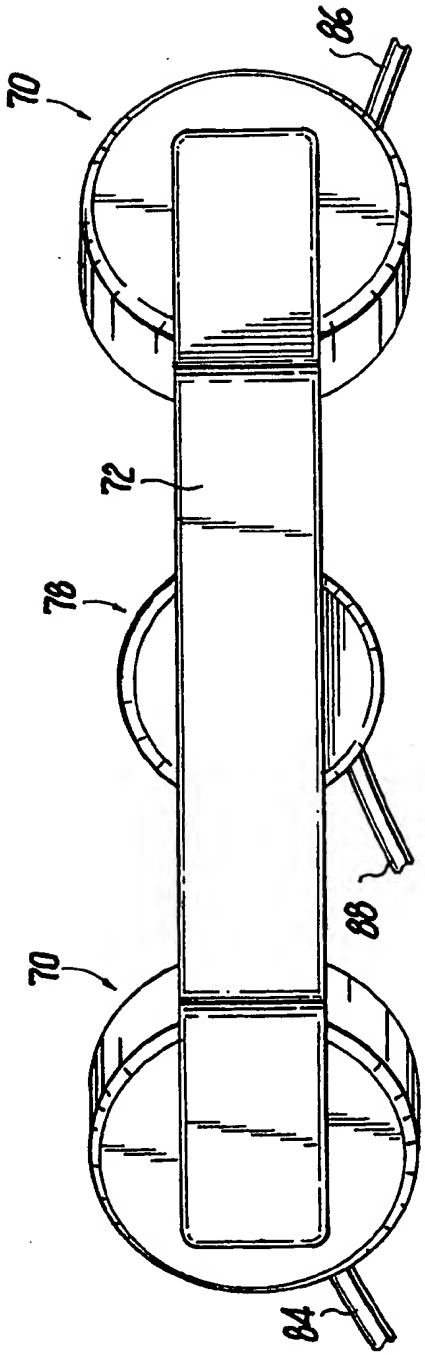


Fig. 16A

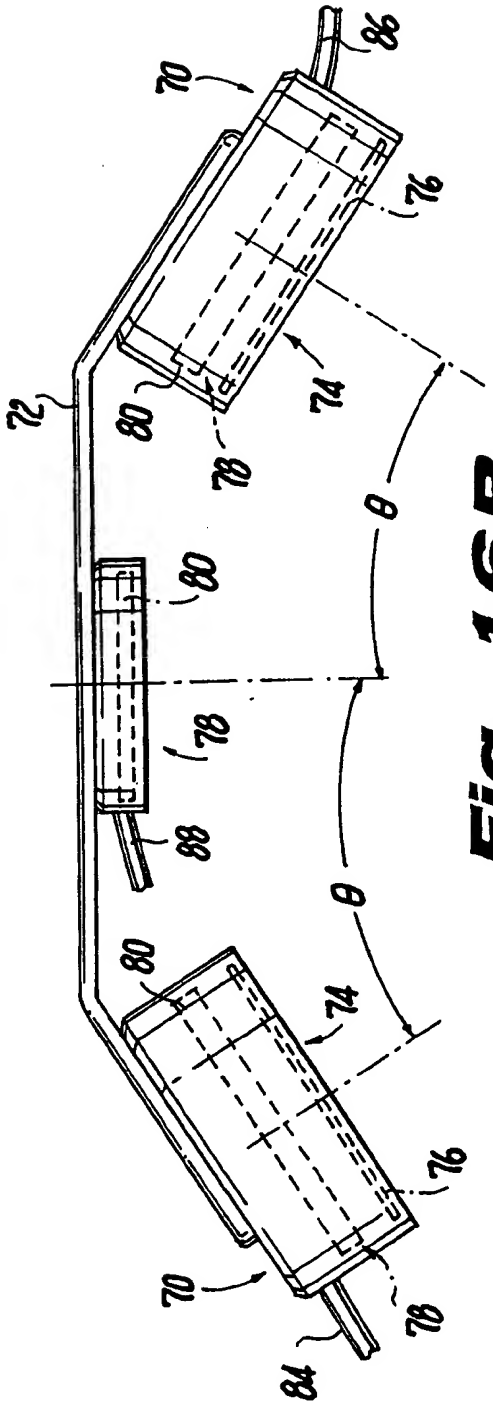


Fig. 16B

INTERNATIONAL SEARCH REPORT

Inter onal Application No
PCT/US 00/13649

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61N7/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61N A61H

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, WPI Data, PAJ, BIOSIS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 196 13 425 A (MENTOP ELEKTRONIC GMBH) 16 January 1997 (1997-01-16)	24
A	column 2, line 59 - line 63 column 3, line 15 - line 20; figure 1	1
X	US 5 741 317 A (OSTROW ALVIN STEWART) 21 April 1998 (1998-04-21)	24
A	column 4, line 37 - line 48 column 4, line 60 - line 67; figure 1	1
X	US 5 476 438 A (EDRICH JOCHEN ET AL) 19 December 1995 (1995-12-19)	24
A	column 4, line 48 - line 61; figure 3	1
X	US 5 738 625 A (GLUCK DANIEL S) 14 April 1998 (1998-04-14)	24,25
A	column 9, line 1 - line 13; figure 5	1

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
24 August 2000	31/08/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Mayer, E

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/US 00/13649

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 556 372 A (URGOVITCH KENNETH J ET AL) 17 September 1996 (1996-09-17) cited in the application column 6, line 65 -column 7, line 5; figure 2	1,24

INTERNATIONAL SEARCH REPORT

nformation on patent family members

Inter onal Application No
PCT/US 00/13649

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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